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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/449,093	11/24/1999	DOV HARTAL	4118	5856

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BROWDY AND NEIMARK, P.L.L.C.  
624 NINTH STREET, NW  
SUITE 300  
WASHINGTON, DC 20001-5303

EXAMINER
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SHERRER, CURTIS EDWARD

ART UNIT	PAPER NUMBER
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1761

DATE MAILED: 08/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/449,093

Applicant(s)

HARTAL ET AL.

Examiner

Curtis E. Sherrer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06/10/03.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14, 23-38 and 41-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14, 23-38 and 41-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

Claims 1-14, 23-28, 44 and 45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants directed the examiner's attention to page 9, line of the instant specification but this only provides a basis for the concentration of lycopene rather than the "coloring material." Applicants argue that "the lycopene of the present invention is encapsulated within the chromoplast and this is clear for Applicant's specification as a whole . . . ." Again, applicants have provided no specific basis for this argument. The specification discloses that the coloring material contains partially broken chromoplasts and therefore it is reasonable that the instant coloring material contains lycopene in intact chromoplasts; lycopene in partially broken chromoplasts, and; lycopene free from broken chromoplasts. How much is in each form is not disclosed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14, 23-28 and 41-45 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Applicants state that processing steps are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Applicants cite to their specification whereby it states "conventional methods of extraction destroy the crystalline structure of this pigment." They state that a "key aspect of the present invention therefor is to liberate the chromoplast from the fruit without causing substantial mechanical breakage or destruction of the chromoplast." Page 9 of Paper #9, After Final Amendment). A review of the specification discloses that the processing of tomatoes to produce the instant product (except for the centrifugation) is "not essentially different [than] those conventionally carried out in the tomato processing industry." It is therefore unclear, at present, what process conditions (extraction steps) are being relied on to keep the chromoplast particles intact.

In response to this rejection, applicants argue that "centrifugation is known to be a gentle process." It is noted that applicants also state that "the solids are separated from the liquid simply by (gently) centrifugation." (Page 3 of their reply). This statement indicates that there are ranges of centrifugation use, ranging from gentle to rough. Applicants do not disclose any specific parameters by which to operate a centrifuge so that it will be gentle.

Applicants refer to their examples to support their argument. A review of the examples show that the color concentrate, after exiting the centrifuge, is subjected to size reduction, in a colloid mill or a microcutter to yield the lycopene. Nothing in the examples mentions chloroplasts.

Applicants state that centrifugation is known to be gentle. This appears to be based on opinion and not evidence and therefore it is not found persuasive.

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In the Hartal Declaration, it is stated that "gentle over-all treatment and breaking of the tomato into its competent parts is essential . . . ." Again, if this is essential, then applicants need to fully disclose what they mean by gentle treatment so that the invention can be practiced.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14, 23-28 and 41-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is indefinite because the scope of the phrase "high lycopene content tomato" is unknown. Applicants respond by citing case law where similar phrases or terms were found to be definite. A term or phrase that at first appears indefinite, due to it being relative term, may be found adequately defined after a review of the specification. Applicants have not provided any basis in their specification for a solid definition of the phrase in question. The fact that certain courts and patent examiners have determined similar phrases to be definite may be due to the disclosure of the specifications before them.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the

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requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1-14, 23-25, 28 and 45 to are rejected under 35 U.S.C. § 102(b)/102(e) as being anticipated by Graves et al (USPN 5,245,095) for the reasons set forth in the last Office Action.

Claims 14, and 41-43 are rejected under 35 U.S.C. § 102(b) as being anticipated by Tannuci et al (Jnl. of Agricultural and Food Chemistry) for the reasons set forth in the last Office Action.

Claims 1-3 and 5-7 are rejected under 35 U.S.C. § 102(b) as being anticipated by Brumlick et al. (U.S. Pat. No. 4,181,743) for the reasons set forth in the last Office Action.

Claims 1-3, 5, 6, 13, and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Szabo et al. (U.S. Pat. No. 3,864,504) for the reasons set forth in the last Office Action.

Claims 1-5 and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bradley (U.S. Pat. No. 4,670,281) for the reasons set forth in the last Office Action.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

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Claims 1-5, 7 and 13 and 14 are rejected under 35 U.S.C. § 102(e) as being anticipated by Lang (U.S. Pat. No. 5,229,160) for the reasons set forth in the last Office Action.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26 and 27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Graves et al. in view of Horn et al (U.S. Pat. No. 4,726,955) for the reasons set forth in the last Office Action.

Claims 1-5, 7, 13 and 14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lang in view of Brumlick et al.) for the reasons set forth in the last Office Action.

Claims 1-14, 24-28 and 45 are rejected under 35 U.S.C. § 103 as being unpatentable Tannuci et al (Jnl. of Agricultural and Food Chemistry) in view of Dale et al. (Jnl. of Food Sci) for the reasons set forth in the last Office Action.

***Response to Arguments***

Applicants' arguments filed 06/10/03 have been fully considered but they are not persuasive.

Applicants argue that the products analyzed by Tonnucci do not anticipate the claimed food products because they contain possess a Brix values higher than that claimed in the coloring material claims. Because the product claims on need to possess the characteristics of the claimed coloring materials and do not require that the Brix values cannot be higher. Further, some of the Tonnucci products contain low Brix values, but then have lower amounts of lycopene than claimed. But these products also would anticipate the claimed food product as they contain all the elements of the claimed coloring material. It is noted that the Declaration is silent as to the teachings of Tonnucci.

Applicants argue that Graves does not anticipate the rejected claims because Graves works with the liquid fraction. In response, it is noted that the instant claims are not restricted to non-liquid fractions. The Declaration also states that Graves' cell disruption "certainly means of destruction of the chromoplast membrane." This statement is not based on any evidence and therefore is not found persuasive. Applicants certainly disrupt cells in order to obtain their claimed product, and it is not seen that Graves does anything differently.

It is noted that graves teaches that "separation of carotenoid-enriched solid precipitate portion from the carotenoid-depleted liquid portion may be achieved by any conventional method, including centrifugation . . . ." (Col. 4, lines 51-56).

The rejection based on Iwatsuki is withdrawn. It appears that the concentrates tested by Iwatsuki had an amount of lycopene below the claimed amount. This calculation was based on knowing the amount of lycopene per gram of fruit (Table 1) and that 40 grams of fruit were extracted in the experiment.



The rejection based on Dale is withdrawn, because it is believed that the final products of Dale would contain a soluble solid content higher than that claimed.

Applicants argue that Brumlick is non-enabling because the liquid rather than the solid fraction is worked with. It is noted that the solid material removed in the Brumlick process will contain the lycopene.

Applicants state that Szabo heats the serum, which would destroy the lycopene/chromoplast structure. When the serum is heated, the "red colored fraction of colloids" has been removed and therefore the heating will not affect these. Applicants also state that the present invention has neither a tomato smell nor taste. It appears that only the serum is taught to have the flavor and aroma of tomatoes. See col. 2, lines 38-42.

Applicants argue that Bradley and Lang heat their tomato material and therefore, as argued above, the chromoplast would be degraded. The heating by Bradley is an alternative to "the fresh tomatoes may be macerated initially utilizing the cold-break method." (Col. 3, lines 10-11). With respect to the teachings of Lang, again, applicants still have provided no evidence as to what temperatures and times degrade chromoplasts or lycopene. If such processing parameters are critical to the practice of the instant invention, then such parameters should be disclosed.

With regard to the obviousness rejections, applicants argue that the secondary references to not make up for the deficiencies of the primary reference and therefore rejections are improper. It is respectfully considered that the rejections meet all the limitations of the claims and therefore a *prima facie* case of obviousness exists.

***Conclusion***

This is a RCE of applicants' Application No. 09/449,093. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Curtis E. Sherrer whose telephone number is 703-308-3847. The examiner can normally be reached on Tuesday-Friday, 8AM-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on 703-308-3959. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3602 for regular communications and 703-305-3602 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

A handwritten signature in black ink, appearing to read 'C. E. Sherrer', with a long horizontal flourish extending to the right.

Curtis E. Sherrer  
Primary Examiner  
July 30, 2003